A fifteen-year experience with carotid endarterectomy after a formal operative protocol requiring highly frequent patch angioplasty

Joseph P. Archie, Jr, PhD, MD, *Raleigh, NC*

Purpose: The early and late outcomes of carotid endarterectomy (CEA) following a rigid protocol of patch angioplasty or occasionally interposition bypass grafting, when the arteriotomy required to obtain a complete internal carotid end point extended distal to the bulb segment, and primary closure, when it was limited to the bulb, were studied.
Methods: From November 1983 to August 1998, 1360 consecutive primary CEAs were performed on 1133 patients (621 men, 512 women), with a mean age of 67 years. Of these patients, 3.8% (51) had primary closure, 66.4% (903) had greater saphenous vein patch angioplasty, 28.4% (386) had synthetic (359 Dacron, 27 polytetrafluoroethylene) patch angioplasty, and 1.4% (20) had vein interposition bypass grafting procedures. Indications were transient ischemic attack in 34.7% of patients (472), stroke in 16.6% of patients (226), nonlateralizing symptoms in 10.9% of patients (148), and asymptomatic stenosis 70% or greater in 37.8% of patients (514). The mean follow-up period was 4.6 years.
Results: The 30-day mortality rate was 1.0% (13 patients; 11 cardiac-related deaths, 2 strokes). The 30-day stroke rate was 1.3% (18 patients; 13 ipsilateral strokes, 5 major, 8 minor). The combined 30-day stroke and death rate was 2.1%. Four of the strokes (1 death) were caused by the hyperperfusion syndrome. The 30-day ipsilateral major stroke or mortality rate was 1.2% (16 patients). The 30-day rate of ipsilateral major stroke or death from stroke was 0.4% (5 patients). There were two synthetic and one vein patch internal carotid occlusions in 30 days. Synthetic-patched CEAs were predicted by means of Cox proportional hazards analysis to have higher risk ratios than saphenous vein-patched CEAs for early and late stroke (1.3; 95% CI, 1.7 to 1.0; $P = .04$), for 50% or greater restenosis (2.4; 95% CI, 3.4 to 1.6; $P < .001$), and for 70% or greater restenosis (2.5; 95% CI, 3.6 to 1.7; $P < .001$). The cumulative mortality rate (Kaplan-Meier) was 13% at 5 years and 31% at 10 years. The cumulative stroke rate was 7% at 5 years and 14% at 10 years. The 50% or greater restenosis rate was higher in women than in men at 5 years (9% versus 5%; $P = .02$, Wilcoxon), but tended to equalize later. The 50% or greater restenosis rate was higher in synthetic-patched CEAs than in saphenous vein-patched CEAs (12% versus 1% at 1 year; 17% versus 3% at 4 years; and 24% versus 10% at 8 years; $P < .001$ by means of log-rank and Wilcoxon). Restenosis after 5 years was more frequently located in the distal common carotid artery (13 of 20 cases). Late reoperations were more frequent and occurred earlier in synthetic-patched CEAs (eight cases at a mean of 1.6 years) than vein-patched CEAs (14 cases at a mean of 6.9 years; $P = .01$). No strokes and one restenosis of 50% or greater occurred in the 51 primarily closed CEAs.
Conclusion: Patch angioplasty reconstruction of CEAs with arteriotomies that extend distal to the carotid bulb gives excellent early and long-term outcomes. Saphenous vein-patched CEAs are superior to synthetic patched CEAs for stroke and restenosis prevention. Primary closure is safe and durable when complete end points and arteriotomies are within the carotid bulb. (J Vasc Surg 2000;31:724-35.)

From the Carolina Cardiovascular Surgical Associates and Wake Medical Center.

Competition of interest: nil.

Presented as a poster at the Forty-seventh Joint Annual Meeting of The Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery, Washington, DC, June 6–9, 1999.

Reprint requests: Joseph P. Archie, Jr, MD, Carolina Cardiovascular Surgical Associates, 3000 New Bern Ave, Suite 1100, Raleigh, NC 27610.

0741-5214/2000/$12.00 + 0 24/1/104591
doi :10.1067/mva.2000.104591

More than two decades ago, Sundt and Imparato recognized that carotid endarterectomy (CEA) patch angioplasty reconstruction with autologous greater saphenous vein improved patients' outcomes.[1,2] Other authors also reported better results with patch reconstruction than with primary closure.[3-6] Subsequently, a number of small prospective randomized trials comparing patch angioplasty with primary closure were carried out, with mixed results.[7-12] However, meta-analysis of the pooled data from these trials indicates the statistically powerful advantage of obligatory patch angioplasty over obligatory primary closure for early postoperative internal carotid occlusions, perioperative stroke, and 50% or greater restenosis at 1 year.[13-15] Analysis of studies containing a nonrandomized mix of primarily closed and patched CEAs suggests that the higher the incidence of patching, the lower the perioperative stroke rate.[14] Although the popularity of CEA patch reconstruction has grown in the last decade, the choice of patch material has become controversial. Recent reports suggest saphenous vein may be superior to synthetic materials.[16,17] Further, pooled meta-analysis data indicate that autologous greater saphenous vein-patched CEAs have a significantly lower incidence of perioperative stroke and early restenosis than do Dacron- and polytetrafluoroethylene (PTFE)-patched CEAs.[18,19] If patch angioplasty reconstruction is advisable for most CEAs and autologous greater saphenous vein is the optimal patch material, it is important to establish the early and long-term outcomes of this approach.

Beginning in November 1983 and continuing to date, a formal protocol of primary CEA reconstruction has been uniformly followed. Obligatory patch angioplasty, or rarely interposition bypass grafting, is used when the arteriotomy required to obtain a complete internal carotid end point extends distal to the bulb segment. Primary closure is performed only when a complete feathered end point is obtained in the bulb segment, with an arteriotomy that does not extend beyond the bulb, an infrequent event. The favorable early outcome of the first 100 CEAs performed that followed this protocol has been reported.[4] A 3-year follow-up analysis of a recent subset of Dacron- and greater saphenous vein-patched CEAs indicates that restenosis is higher in Dacron-patched CEAs and that the eversion plication shortening of redundant endarterectomized internal carotid artery segments may lead to restenosis.[17] Although these early results are included, the purpose of this report is to define the perioperative, short- and long-term outcomes for the entire series of primary CEAs performed following the protocol.

METHODS AND MATERIALS

Patient demographics, risk factors, and anatomy. From November 1983 to August 1998, 1360 consecutive primary CEAs were performed by the author, who followed a strict operative protocol of patch angioplasty, or rarely interposition bypass grafting, when the arteriotomy required to obtain a complete internal carotid end point extended distal to the bulb segment, and primary closure (PC), when it was limited to the bulb. Of the 1360 CEAs, 621 (134 bilateral) were performed on men, and 512 (93 bilateral) were performed on women. The mean patient age was 67.5 ± 9.0 years (mean ± SD), slightly higher in women (68.4 ± 9.3 years) than in men (66.9 ± 8.8 years). There were 671 right CEAs and 689 left CEAs. The indications for CEA were transient ischemia attacks in 473 cases (34.7%), completed nondebilitating stroke in 226 cases (16.6%), nonlateralizing or global symptoms in 148 cases (10.9%), and asymptomatic 70% or greater diameter stenosis in 514 cases (37.8%). One hundred thirty-eight (26.8%) of the 514 CEAs for asymptomatic stenosis were the second sides of bilateral CEAs, the first side of which was the source of symptoms in 65 cases and asymptomatic in 73 cases. Systemic risk factors included previous or current cigarette smoking in 1080 patients (79.4%), hypertension in 823 patients (60.5%), known coronary artery disease in 921 patients (67.7%), of whom 128 patients (9.4%) had previously undergone coronary artery bypass grafting procedures, and diabetes mellitus in 186 patients (13.7%).

Preoperative standard or arterial digital arteriography was performed on most patients. In 237 more recently treated patients, the degree of stenosis was determined by means of duplex ultrasound scanning, occasionally supplemented by magnetic resonance angiography. The operated carotid diameter stenosis was 77.9% ± 21.9%. The contralateral internal carotid artery was occluded in 98 patients (67 men, 31 women). Excluding these patients, the contralateral carotid stenosis was 33.1% ± 29.8%. During this time, 19 internal carotid arteries were found to be small or poorly visualized (string sign) by means of arteriography. Of these, eight carotid arteries were either occluded or small and fibrotic with low flow and were not repaired. These eight carotid arteries are not included in this series, nor are any isolated procedures performed on the external carotid artery when the internal carotid was occluded.

CEA was performed concurrent with coronary bypass grafting procedures before opening the ster-

Table I. Time course of operations by reconstruction type

Years	*1983 to 1985*	*1986 to 1987*	*1988 to 1989*	*1990 to 1991*	*1992 to 1993*	*1994 to 1995*	*1995 to 1998*	*Total*
All	235	205	166	178	200	199	177	1360
Primary closure	12	6	12	6	2	8	5	51
Patch–all	222	190	151	172	196	187	171	1289
Saphenous vein	217	182	133	150	155	59	7	903
Dacron	5	7	1	15	39	128	164	359
PTFE	0	1	17	7	2	0	0	27
Vein interposition bypass grafting	1	9	3	0	2	4	1	20

PTFE, Polytetrafluoroethylene.

num in 73 patients (5.4%). Four patients had combined infrarenal aortic procedures and CEA, and two patients had combined lower-extremity bypass grafting procedures and CEA. Ipsilateral vertebral artery transposition to the common carotid artery was performed in seven cases.

Operative management. General anesthesia was used for all operations, except eight operations that were performed with a regional block. Saphenous veins were harvested from the groin / thigh in most women and below the knee / ankle in men. Standard surgical techniques, including careful dissection before occlusion, optical magnification, systemic heparin, and meticulous deep media endarterectomy and end point management, were used. Jugular venous and carotid stump back pressure were measured in all procedures, and a shunt was inserted in 156 cases (9.6%) when the mean cerebral perfusion pressure (mean stump minus mean venous pressure) was less than 18 mm Hg. The criteria for not shunting when perfusion pressure was 18 mm Hg or greater have been strictly followed for 20 years and were derived to ensure a collateral blood flow of 18 mL / min / 100 g or greater.[20] The mean systemic arterial pressure was 81.7 ± 13.4 mm Hg; the mean stump pressure was 43.2 ± 16.8 mm Hg; the mean jugular venous pressure was 5.8 ± 3.2 mm Hg; and the mean cerebral perfusion pressure was 37.4 ± 16.8 mm Hg. For the 98 CEAs (7.2%) with contralateral internal carotid occlusion, the mean perfusion pressure was 24.4 mm Hg, compared with 38.6 mm Hg when the CEA was patent ($P < .001$). The arteriotomy required to achieve a complete internal carotid endarterectomy end point was within the bulb segment in 51 CEAs (3.8%), and all these were primarily closed. The arteriotomy extended into the uniform diameter internal carotid in the other 1309 CEAs, of which 903 CEAs (66.4%) had patch reconstruction with autologous greater saphenous vein, 386 CEAs (28.4%) had synthetic patch reconstruction (359 Dacron, 27 PTFE), and 20 CEAs (1.4%) had saphenous vein interposition bypass grafts. The latter were used in the rare cases in which the endarterectomized segment was extremely long or severely damaged by disease or endarterectomy. Internal carotid end point tacking sutures were used in 33 CEAs (2.4%). Eversion plication shortening of the endarterectomized internal carotid segment was performed in 156 CEAs (11.5%). Most of these were performed in Dacron-patched CEAs. When I began frequent use of Dacron in 1994, I noticed that this patch material resulted in a much higher incidence of kinking distally. Accordingly, shortening was performed more often.[17] Table I gives the reconstruction methods used in 2- to 3-year intervals.

Intraoperative bidirectional continuous-wave Doppler ultrasound scanning interrogation was done after all CEA reconstructions. When the external carotid was occluded or had low flow, it was isolated and repaired.[21] A significant kink or other technical major defect was noted in the internal carotid after six CEAs, and these were reconstructed a second time to eliminate the problem.

Postoperatively all patients were monitored with electrocardiography and radial arterial blood pressure readings overnight. Systolic blood pressure was maintained at 160 mm Hg or less. Beginning in 1990, all patients with severe ipsilateral headache were observed for the hyperperfusion syndrome, and hypertension was treated aggressively. In spite of these occasional patients, the mean postoperative hospital stay was reduced from an earlier mean of 3.7 days to 1.6 days after 1994. Patients with clear or questionable perioperative neurologic events were examined by a neurologist and underwent a duplex scan, an arteriogram, or both and either a computed tomography or magnetic resonance imaging scan. All patients who awoke from general anesthesia with a new, unexplained neurological defect and patients in whom a deficit developed before discharge and who had abnormal results on a duplex scan or arteriogram were reexplored.

Table II. Perioperative hospital and posthospital 30-day death and stroke rate for 1360 carotid endarterectomies

	Hospital		Posthospital		All 30-day	
	N	*% (± 95% CI)*	*N*	*% (± 95% CI)*	*N*	*% (± 95% CI)*
Death						
All	9	0.7% (0.4%)	4	0.3% (0.2%)	13	1.0% (0.5%)
Cardiac	8	0.6% (0.4%)	3	0.2% (0.1%)	11	0.8% (0.5%)
Stroke	1	0.07% (0.05%)	1	0.07% (0.05%)	2	0.1% (0.07%)
Stroke*						
All	11	0.8% (0.5%)	7	0.5% (0.4%)	18	1.3% (0.6%)
Ipsilateral	8	0.6% (0.4%)	5	0.4% (0.3%)	13	1.0% (0.5%)
Major	3	0.2% (0.17%)	2	0.1% (0.07%)	5	0.4% (0.3%)
Minor	5	0.4% (0.3%)	3	0.2% (0.1%)	8	0.6% (0.4%)
Ipsilateral stroke etiology						
ICA thrombosis	0	–	0	–	0	–
Operative embolic	4	0.3% (0.2%)	–	–	–	–
Shunt embolic†	2	0.1% (0.07%)	–	–	–	–
Hyperperfusion	0	–	4	0.3% (0.2%)	4	0.3% (0.2%)
Unknown‡	2	0.1% (0.07%)	1	0.07% (0.05%)	3	0.2% (0.5%)
Ipsilateral stroke type reconstruction						
Vein (n = 903)	3	0.2% (0.5%)	4	0.3% (0.2%)	7	0.5% (0.4%)
Dacron (n = 359)	5	0.4% (0.3%)	1	0.07% (0.05%)	6	0.45% (0.35%)
PTFE (n = 27)	0	–	0	–	0	–
Bypass (n = 20)	0	–	0	–	0	–
Primary closure (n = 51)	0	–	0	–	0	–

*Includes two stroke-related deaths.
†Emboli seen in shunt.
‡Normal results on duplex scan or arteriogram.
ICA, Internal carotid artery; *PTFE,* polytetrafluoroethylene.

A drain was placed at all operations. Protamine was given in the operating room only when there was excessive bleeding. The incidence of excessive bleeding was approximately 5% and occurred primarily in patients who had been on Coumadin or one of the newer antiplatelet drugs preoperatively. Protamine was given in the recovery room in approximately 8% of patients in whom there was excessive but not alarming drainage or mild hematoma formation. Only nine patients (0.7%) were returned to the operating room for excessive hemorrhage.

Follow-up. Patients were routinely seen in the office 6 to 10 days after CEA. Duplex scanning was advised at 2 months, 6 months, and then annually (Ultra Mark 8 and later Ultra Mark 9, Advanced Technology Laboratories, Bothell, Wash). Criteria for residual or restenosis were: for 50% to 69% stenosis, a peak systolic velocity of 160 cm/s or more and spectral broadening; for 70% or greater stenosis, a peak systolic velocity of 250 cm/s or more and an end-diastolic velocity of 90 cm/s or more. All data were prospectively stored in a computer registry. Letters requesting the patients' current status and recommending duplex scanning were sent annually to surviving patients.

Statistical methods. For categorical variables, the proportion of CEAs with stroke and recurrent stenosis was compared with and without specified characteristics or risk factors. The 95% CIs for proportions were computed from the normal distribution when the numerator was 5 or more. When the numerator was less than 5, the binomial distribution was used. Differences in proportions were tested with either a two-tailed Fisher exact test or chi-square analysis. In addition, the probability of stroke and recurrent stenosis, with and without specific characteristics or risk factors, was analyzed by means of Kaplan-Meier survival analysis with *P* values by means of log-rank (long term) and Wilcoxon (short term) methods and/or Cox proportional hazards analysis. Continuous variables were analyzed with unpaired Student *t* tests or analysis of variance. Those characteristics and risk factors that had *P* values near or less than .05 by means of univariant analysis were subjected to multivariant analysis with logistic regression and/or Cox proportional hazards analysis to obtain odds or risk ratios and the 95% CI. Summary statistics are given as mean ± 1SD. All data were prospectively stored in a computer registry, and statistics were computed with JMP 3.0 software (SAS Institute, Cary, NC).

RESULTS

Perioperative stroke and mortality. The 30-day hospital and posthospital death and stroke rates, including the etiology of stroke and the type of reconstruction, are given in Table II. There were 13 (1.0%) 30-day deaths, 11 of which were cardiac-related (two with concomitant coronary artery bypass grafting) and two were from stroke. Of the 11 30-day perioperative cardiac-related deaths, nine occurred between 1983 and 1990 (695 CEAs), and the other two occurred between 1991 and 1998 (665 CEAs; $P = .084$). There were 18 strokes (1.3%) in 30 days, 13 of which were ipsilateral, four were contralateral (one with coronary artery bypass grafting), and one was posterior. Four of the strokes (one death) were caused by the hyperperfusion syndrome. Overall, this syndrome developed in eight patients (0.6%) from 4 to 8 days after CEA. This small subset of patients was characterized as having high-grade stenosis (mean, 87%; $P < .01$ when compared with other CEAs) and low carotid stump back pressure (mean, 27 mm Hg; $P < .001$ when compared with other CEAs). Hemorrhage was found with computed tomography or magnetic resonance imaging scanning in only one of these eight patients. Five of the eight ipsilateral hospital strokes were identified immediately on the patient's awakening from general anesthesia. Four of these patients had both normal results on a duplex scan and an operative explanation. In two patients, atheroemboli were seen in the shunt after placement. One patient had a preoperatively unrecognized atherosclerotic ulcer approximately 1 cm distal to the stenosis in the internal carotid artery, which was manipulated before clamping, and in one patient plaque was visualized in the clamp at the origin of the external carotid during isolated repair after an occluded external carotid was indicated by means of intraoperative Doppler interrogation.[21] The fifth patient was reoperated on and found to have platelet thrombus on a Dacron patch. Four of the seven ipsilateral strokes in the vein-patched CEA group were caused by the hyperperfusion syndrome. The incidence of nonhyperperfusion ipsilateral perioperative stroke in the vein-patched group was 0.3% (3 of 903 patients), significantly less than 1.7% (6 of 359 patients) for patients with Dacron-patched CEAs ($P = .022$). For nonshortened CEAs, the incidence of nonhyperperfusion ipsilateral perioperative stroke was 0.3% (3 of 873 patients) for vein-patched CEAs, significantly less than the 2.1% (5 of 234 patients) for Dacron-patched CEAs ($P = .014$). Two of the six patients who had ipsilateral strokes in the Dacron-patched CEA group had an unstable neurological status and underwent semiurgent operations.

Minor perioperative morbidity. Nineteen (0.8%) ipsilateral transient ischemic attacks were identified, seven of which were identical to preoperative symptoms. All patients had a duplex scan, 13 of which were normal, including the seven discussed earlier; four patients had a 2 mm or greater endarterectomy-produced common carotid artery step,[22] and two patients had a kink in the internal carotid at the distal end of a patch. None of these patients had a stroke, and one patient with a kink underwent a reoperation for progression to 80% diameter stenosis 2 years after primary CEA. Thirteen nonfatal myocardial infarctions occurred, six of which were subendocardial. Eleven of these patients subsequently underwent coronary artery bypass grafting procedures. Cervical / cranial nerve dysfunction occurred in 10 patients (0.7%). Two recurrent laryngeal nerve injuries were permanent, and five were transient. Two transient and one permanent hypoglossal nerve injuries and one greater auricular nerve injury occurred. Ventricular tachyarrhythmias occurred in four patients and were managed medically. Clinically significant hematomas or drainage necessitating operative exploration occurred in nine patients (0.6%). Of these cases, two were caused by saphenous vein patch rupture, one from suture hole bleeding of a PTFE patch and one from a repair of the external carotid artery. The other five patients had no identified source of bleeding at re-exploration. No neck infections occurred. Eight patients had minor vein harvest incision infections, six in the thigh and two in the lower leg.

Saphenous vein patch rupture. As previously reported, central vein patch rupture occurred after three CEAs.[23,24] One rupture occurred in the operating room, one occurred in the hospital, and one occurred after discharge. All patients underwent successfully reoperations. Only the patient in whom the rupture occurred after discharge had a minor stroke that resolved. After 1990, veins with less than 3.5 mm distended diameters were not used, and there have been no ruptures.[24]

Long-term stroke and mortality. The 10-year Kaplan-Meier survival analysis is given in Fig 1 (Table III). Although the etiology of late death was primarily cardiac-related, in many patients it was difficult to determine from the communication with their primary care physicians and / or families. The 10-year Kaplan-Meier analysis of all strokes is given in Fig 2 (Table IV). Although perioperative ipsilateral stroke was clearly identifiable from contralateral or posterior territory stroke, this clarification was not possible for some patients who had late strokes. Univariant analysis of the possible role of sex, sys-

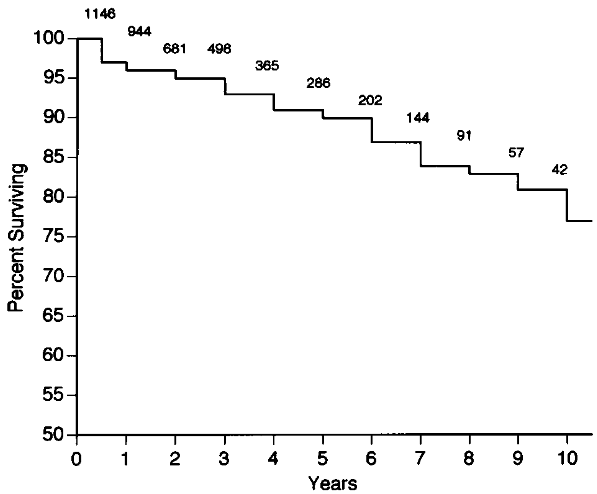

Fig 1. Kaplan-Meier life-table analysis of survival after the 30-day postoperative period.

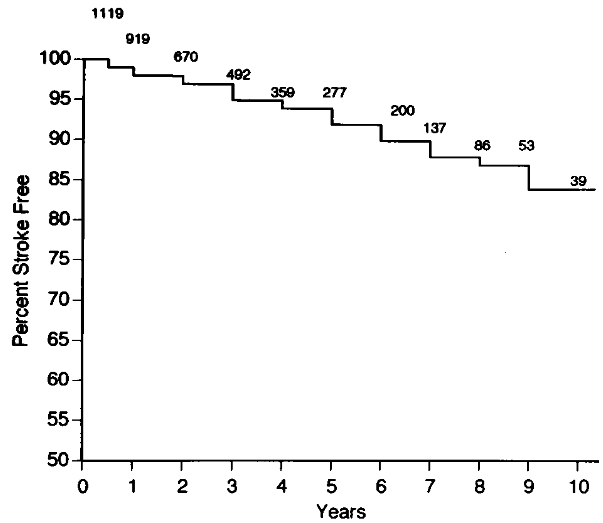

Fig 2. Kaplan-Meier life-table analysis of all strokes after the 30-day postoperative period.

temic risk factors (smoking, hypertension, diabetes mellitus, and coronary artery disease), indications for operation, and the technical / reconstructive variables (closure type, patch material, internal carotid shortening, internal carotid tack sutures, use of a shunt, and combined CEA and cardiac surgery) on early and late stroke indicated that only sex and patch material had a P value less than .10. By means of Cox proportional hazards analysis, women were predicted to have a slightly higher relative risk ratio for stroke than men (1.03; 95% CI, 1.09 to 0.97; P = .29). By means of Cox analysis, Dacron-patched CEAs were predicted to have a higher risk ratio for stroke than saphenous vein-patched CEAs (1.3; 95% CI, 1.7 to 1.0; P = .04).

For patients in whom the side of the stroke was known, stroke was found to be more frequent on the ipsilateral side of patients undergoing unilateral CEA than on the contralateral side by means of Cox analysis (risk ratio, 3.4; 95% CI, 6.4 to 1.9; P < .001). Patients undergoing bilateral operations had a slightly but significantly higher risk ratio for stroke than those undergoing unilateral CEA (1.10; 95% CI, 1.18 to 1.03; P = .005). Finally, contralateral occlusion did not significantly increase stroke risk, when compared with patients having unilateral CEA with patent contralateral internal carotids (1.18; 95% CI, 2.27 to 0.73; P = .54).

Residual and recurrent stenosis. Table V gives the univariant analysis of 50% or greater residual stenosis detected less than 4 months after CEA, and the 50% or greater and 70% or greater early recurrent stenosis 4 months to 3 years after CEA for the reconstruction types and patch materials used. Three early asymptomatic internal carotid occlusions occurred, two in Dacron-patched CEAs and one in a vein-patched CEA. All four residual stenoses were caused by kinking at the distal end of a patch. One of these residual stenoses was identified intraoperatively by means of continuous-wave Doppler scanning, but was not repaired. The Kaplan-Meier analysis for 50% or greater and 70% or greater recurrent stenosis for men and women is given in Fig 3 (Table VI) and Fig 4 (Table VII). The Kaplan-Meier analysis for 50% or greater and 70% or greater recurrent stenosis for saphenous vein-patched, synthetic-patched, and primarily closed CEAs is given in Fig 5 (Table VIII) and Fig 6 (Table IX). Although synthetic-patched CEAs have a tendency to restenose early, restenosis in vein-patched CEAs is prevalent after 5 years. However, because most synthetic patches were placed after 1993, the follow-up after 5 years in this subset is insufficient to draw conclusions for late restenosis. Synthetic-patched CEAs were predicted by means of Cox proportional hazards analysis to have significantly higher relative risk ratios than vein-patched CEAs for 50% or greater restenosis (2.4; 95% CI, 3.4 to 1.6; P < .0001) and for 70% or greater restenosis (2.5; 95% CI, 3.6 to 1.7; P < .001). Restenosis after 5 years was most commonly located in the distal common carotid near the endarterectomy-produced step (13 of 20 cases).

The influence of eversion plication shortening of the redundant endarterectomized internal carotid segment has been previously analyzed for the CEAs performed from 1992 to 1997 with saphenous vein- and Dacron-patch angioplasty.[17] The slightly larger

Table III. Kaplan-Meier life-table for survival after 30-day postoperative period (Fig 1)

Years	*Cumulative survival*	*Cumulative mortality*	*Standard error*	*Mortality*	*Censored*	*At risk*
0.0000	1.0000	0.0000	0.0000	0	205	1146
0.5000	0.9745	0.0255	0.0051	24	236	941
1.0000	0.9645	0.0355	0.0063	7	176	681
2.0000	0.9529	0.0471	0.0078	6	127	498
3.0000	0.9346	0.0654	0.0103	7	72	365
4.0000	0.9052	0.0948	0.0139	9	75	286
5.0000	0.8962	0.1038	0.0151	2	56	202
6.0000	0.8713	0.1287	0.0191	4	49	144
7.0000	0.8426	0.1574	0.0247	3	31	91
8.0000	0.8278	0.1722	0.0283	1	14	57
9.0000	0.8081	0.1919	0.0338	1	17	42
10.0000	0.7744	0.2256	0.0462	1	10	24

Table IV. Kaplan-Meier life-table for stroke-free intervals 30-day postoperative period (Fig 2)

Years	*Cumulative stoke-free*	*Cumulative stroke*	*Standard error*	*Stroke*	*Censored*	*At risk*
0.0000	1.0000	0.0000	0.0000	0	200	1119
0.5000	0.9869	0.0131	0.0037	12	237	919
1.0000	0.9781	0.0219	0.0052	6	172	670
2.0000	0.9682	0.0318	0.0068	5	128	492
3.0000	0.9520	0.0480	0.0093	6	76	359
4.0000	0.9417	0.0583	0.0110	3	74	277
5.0000	0.9228	0.0772	0.0142	4	59	200
6.0000	0.9026	0.0974	0.0181	3	48	197
7.0000	0.8816	0.1184	0.0230	2	31	86
8.0000	0.8650	0.1350	0.0279	1	13	53
9.0000	0.8428	0.1572	0.0349	1	16	39
10.0000	0.8428	0.1572	0.0349	0	9	22

numbers of shortened CEAs in the current series have similar high 50% or greater restenosis rates in the first 3 years after CEA. Of the 903 vein-patched CEAs, 30 (3.3%) were shortened, whereas 125 of the 359 Dacron-patched CEAs (35%) were shortened. No difference in 50% or greater restenosis existed at 3 years for shortened (0) versus unshortened (5) vein-patched CEAs (P = .8), or for shortened (11) versus unshortened (10) Dacron-patched CEAs (P = .13). However, by means of univariant analysis, the 50% or greater restenosis rate at 3 years for shortened CEAs (11 of 155, 7.1%) versus unshortened CEAs (15 of 1007, 1.5%) was significant (P < .001).

DISCUSSION

The perioperative, intermediate, and long-term outcomes reported in this study support the highly frequent use of patch angioplasty reconstruction of standard CEAs, following a protocol of using primary closure only when a complete internal carotid end point is obtained with an arteriotomy limited to the bulb segment. The 30-day perioperative mortality of 1.0% ± 0.5% (95% CI), stroke rate of 1.3% ± 0.6%, ipsilateral stroke rate of 1.0% ± 0.5%, combined all stroke and mortality rate of 2.1% ± 0.3%, and major ipsilateral stroke or death rate of 0.4% ± 0.3% are all within the accepted upper threshold for CEA outcomes for both symptomatic and asymptomatic patients. Further, these 30-day outcomes are three- to five-times better than those of the North American Symptomatic Carotid Endarterectomy Trial (NASCET) studies[25,26] and equal to the excellent results of the Asymptomatic Carotid Atherosclerosis (ACAS) study.[27] The cumulative stroke rates of 7% at 5 years and 14% at 10 years and the cumulative mortality rates of 13% at 5 years and 31% at 10 years are similar to that reported in other studies.[28,29] The restenosis rates are low and have a bimodal distribution in the first 2 years, and again after 5 years. Univariant and Cox proportional hazards analyses indicate that only sex (women more than men) and patch material (synthetics more than saphenous vein) significantly influenced late stroke and restenosis outcomes.

The 1983 to 1998 distribution of 30-day deaths is of interest. During the first half of this study, nine cardiac-related deaths occurred, compared with only two cardiac-related deaths during the second half or the study (P = .08). Although not statistically significant, this suggests improved anesthetic manage-

Table V. Residual 50% or greater stenosis and early 50% or greater and 70% or greater restenosis after 1360 carotid endarterectomies

		6 months to 3 years (%)	
Reconstruction (n)	*1 to 3 months (%)*	*50% or greater restenosis*	*70% or greater restenosis*
Primary closure (51)	0	1 (2.0%)	1 (2.0%)
Vein patch (903)	3 (0.3%, 2 kinks, 1 occlusion)	5 (0.6%)	3 (0.3%)
Dacron patch (359)	4 (1.1%, 3 kinks, 1 occlusion)	21 (5.7%)	11 (3.1%)
PTFE patch (27)	0	1 (3.7%)	0
Vein bypass (20)	0	1 (5.0%)	0
All (1360)	7 (0.5%)	29 (2.1%)	15 (1.1%)

$P < .001$ for vein- versus Dacron-patched carotid endarterectomy and vein- versus synthetic-patched carotid endarterectomy for 50% or greater and 70% or greater restenosis at 6 months to 3 years.
PTFE, Polytetrafluoroethylene.

Table VI. Kaplan-Meier life-table for 50% or greater restenosis-free intervals for men and women (Fig 3)

Years	*Cumulative restenosis-free*	*Cumulative restenosis*	*Standard error*	*Restenosis*	*Censored*	*At risk*
Men						
0.0000	1.0000	0.0000	0.0000	0	164	747
0.5000	0.9931	0.0069	0.0034	4	151	583
1.0000	0.9839	0.0161	0.0057	4	109	428
2.0000	0.9776	0.0224	0.0072	2	100	315
3.0000	0.9730	0.0270	0.0085	1	47	213
4.0000	0.9671	0.0329	0.0103	1	51	165
5.0000	0.9671	0.0329	0.0103	0	36	113
6.0000	0.8792	0.1208	0.0330	7	25	77
7.0000	0.8792	0.1208	0.0330	0	18	45
8.0000	0.8466	0.1534	0.0451	1	5	27
9.0000	0.7257	0.2743	0.0753	3	3	21
10.0000	0.6773	0.3227	0.0844	1	6	15
Women						
0.0000	1.0000	0.0000	0.0000	0	111	593
0.5000	0.9876	0.0124	0.0051	6	124	482
1.0000	0.9595	0.0405	0.0100	10	95	352
2.0000	0.9478	0.0522	0.0120	3	53	247
3.0000	0.9280	0.0720	0.0153	4	41	191
4.0000	0.9089	0.0911	0.0185	3	36	146
5.0000	0.9004	0.0996	0.0202	1	33	107
6.0000	0.9004	0.0996	0.0202	0	28	73
7.0000	0.8804	0.1196	0.0280	1	12	45
8.0000	0.8804	0.1196	0.0280	0	13	32
9.0000	0.6951	0.3049	0.0853	4	7	19
10.0000	0.6082	0.3918	0.1103	1	2	8

ment and/or better preoperative evaluation and treatment of coronary artery disease. Although I only refer for cardiology examination those patients who have symptoms of angina pectoris or congestive heart failure, I have noted an increasing trend for patients to have had an earlier examination, coronary angioplasty, or bypass grafting procedure. Only two stroke-related 30-day deaths occurred, one of which was caused by hyperperfusion. Three of the 13 30-day deaths occurred after discharge, supporting the concept that reporting only hospital deaths underestimates the true perioperative incidence.

Of the 18 (1.3%) 30-day strokes, 13 were ipsilateral and five were major or disabling. Seven strokes (five ipsilateral, two major ipsilateral) occurred after discharge. Both of the major strokes were caused by the hyperperfusion syndrome. Nonhyperperfusion-related ipsilateral perioperative strokes were more frequent in the Dacron-patched CEA subset (1.7%) than in the saphenous vein patched CEA subset (0.3%; $P = .02$). This is similar to my earlier findings, those of Hertzer et al, and meta-analysis.[16-19]

In the first 3 months after CEA, only three internal carotid occlusions (two Dacron, one vein patch) were identified, all asymptomatic. Four nonocclusive 50% or greater residual stenoses occurred, all caused

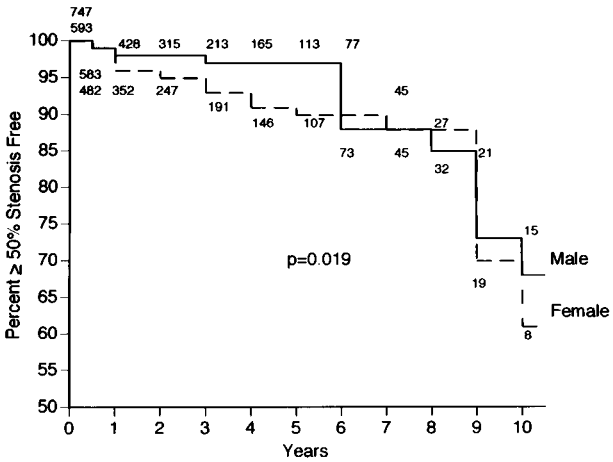

Fig 3. Kaplan-Meier life-table analysis of 50% or greater restenosis-free intervals for men and women (P = .019 by means of Wilcoxon test, and P = .087 by means of log-rank test).

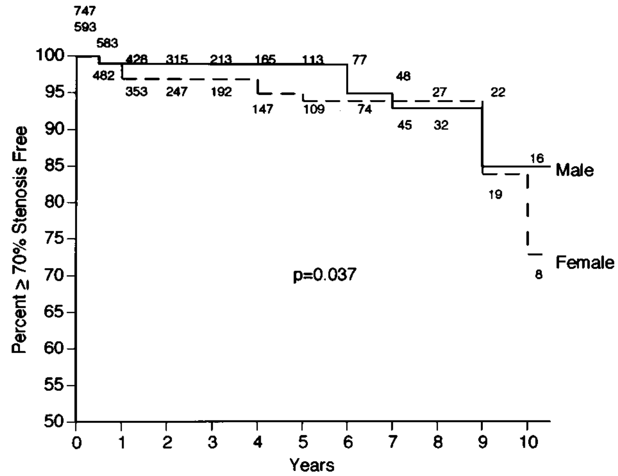

Fig 4. Kaplan-Meier life-table analysis of 70% or greater restenosis-free intervals for men and women (P = .036 by means of Wilcoxon test, and P = .071 by means of log-rank test).

Table VII. Kaplan-Meier life-table for 70% or greater restenosis-free intervals for men and women (Fig 4)

	Years	*Cumulative restenosis-free*	*Cumulative restenosis*	*Standard error*	*Restenosis*	*Censored*	*At risk*
Men							
	0.0	1.000	0.000	0.000	0	164	747
	0.5	0.995	0.005	0.003	3	152	583
	1.0	0.992	0.008	0.004	1	112	428
	2.0	0.992	0.008	0.004	0	102	315
	3.0	0.992	0.008	0.004	0	48	213
	4.0	0.992	0.008	0.004	0	52	165
	5.0	0.992	0.008	0.004	0	36	113
	6.0	0.954	0.046	0.022	3	26	77
	7.0	0.934	0.066	0.029	1	20	48
	8.0	0.934	0.066	0.029	0	5	27
	9.0	0.849	0.151	0.063	2	4	22
	10.0	0.849	0.151	0.083	0	8	16
Women							
	0.0	1.000	0.000	0.000	0	111	593
	0.5	0.994	0.006	0.004	3	126	482
	1.0	0.974	0.026	0.008	7	99	353
	2.0	0.970	0.030	0.009	1	54	247
	3.0	0.965	0.035	0.010	1	44	192
	4.0	0.952	0.048	0.014	2	36	147
	5.0	0.943	0.057	0.016	1	34	109
	6.0	0.943	0.057	0.016	0	29	74
	7.0	0.943	0.057	0.016	0	13	45
	8.0	0.943	0.057	0.016	0	13	32
	9.0	0.844	0.156	0.068	2	9	19
	10.0	0.738	0.262	0.115	1	2	8

by kinks at or distal to the toe of a patch. These were, in theory, preventable by adequate operative technique and / or identification and revision. The rate of restenosis 50% or greater within 3 years of CEA was very low in vein-patched CEAs (0.6%), but significantly higher in both Dacron- (6.4%) and PTFE-patched (3.7%) CEAs. These results are similar to those obtained by meta-analysis.[18,19] As was frequently demonstrated in other studies, women had a higher rate of early restenosis than did men. However, the cumulative incidence of restenosis 5 years after CEA was similar in men and women. Similarly, the cumulative incidence of restenosis in saphenous vein-patched CEAs increased after 5 years.

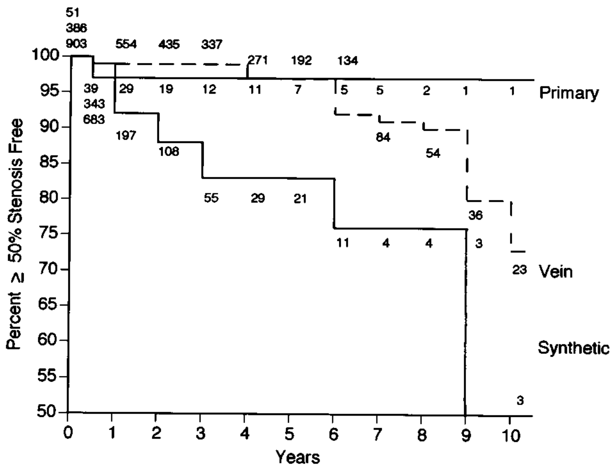

Fig 5. Kaplan-Meier life-table analysis of 50% or greater restenosis-free intervals for vein-patched, synthetic-patched, and primarily closed carotid endarterectomies.

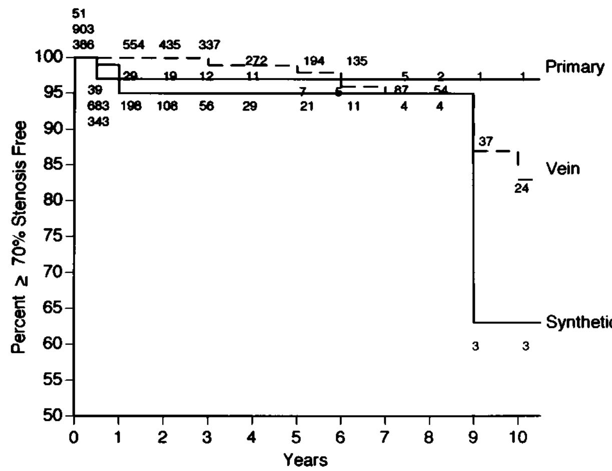

Fig 6. Kaplan-Meier life-table analysis of 70% or greater restenosis-free intervals for vein-patched, synthetic-patched, and primarily closed carotid endarterectomies.

Table VIII. Kaplan-Meier life-table for 50% or greater restenosis-free intervals for vein-patched, synthetic-patched, and primarily closed carotid endarterectomies (Fig 5)

Years	*Cumulative restenosis-free*	*Cumulative restenosis*	*Standard error*	*Restenosis*	*Censored*	*At risk*
Vein						
0.0	1.000	0.000	0.000	0	220	903
0.5	0.994	0.006	0.003	4	125	683
1.0	0.994	0.006	0.003	0	119	554
2.0	0.992	0.008	0.004	1	97	435
3.0	0.986	0.014	0.006	2	64	337
4.0	0.971	0.029	0.009	4	75	271
5.0	0.966	0.034	0.103	1	57	192
6.0	0.923	0.077	0.020	6	44	134
7.0	0.912	0.088	0.022	1	29	84
8.0	0.895	0.105	0.028	1	17	54
9.0	0.796	0.204	0.053	4	9	36
10.0	0.726	0.274	0.067	2	8	23
Synthetic						
0.0	1.000	0.000	0.000	0	43	386
0.5	0.985	0.017	0.006	5	141	343
1.0	0.915	0.085	0.019	14	75	197
2.0	0.882	0.118	0.025	4	49	108
3.0	0.833	0.167	0.036	3	23	55
4.0	0.833	0.167	0.036	0	8	29
5.0	0.833	0.167	0.036	0	10	21
6.0	0.758	0.242	0.079	1	6	11
7.0	0.758	0.242	0.079	0	1	4
8.0	0.758	0.242	0.079	0	0	3
9.0	0.000	1.000	0.079	3	0	3
Primary						
0.0	1.000	0.000	0.000	0	12	51
0.5	0.974	0.026	0.025	1	9	39
1.0	0.974	0.026	0.025	0	10	29
2.0	0.974	0.026	0.025	0	7	19
3.0	0.974	0.026	0.025	0	1	12
4.0	0.974	0.026	0.025	0	4	11
5.0	0.974	0.026	0.025	0	2	7
6.0	0.974	0.026	0.025	0	3	5
7.0	0.974	0.026	0.025	0	0	3
8.0	0.974	0.026	0.025	0	1	2
9.0	0.974	0.026	0.025	0	1	1

Table IX. Kaplan-Meier life-table for 70% or greater stenosis-free intervals for vein-patched, synthetic-patched, and primarily closed carotid endarterectomies (Fig 6)

Years	*Cumulative restenosis-free*	*Cumulative failure*	*Standard error*	*Restenosis*	*Censored*	*At risk*
Vein						
0.0	1.000	0.000	0.000	0	220	903
0.5	0.996	0.004	0.002	3	126	683
1.0	0.996	0.004	0.002	0	119	554
2.0	0.996	0.004	0.002	0	98	435
3.0	0.993	0.007	0.004	1	64	337
4.0	0.985	0.015	0.006	2	76	272
5.0	0.980	0.020	0.008	1	58	194
6.0	0.958	0.042	0.015	3	45	135
7.0	0.948	0.052	0.018	1	32	87
8.0	0.948	0.052	0.018	0	17	54
9.0	0.871	0.129	0.046	3	10	37
10.0	0.834	0.166	0.056	1	10	24
Synthetic						
0.0	1.000	0.000	0.000	0	43	386
0.5	0.994	0.006	0.004	2	143	343
1.0	0.954	0.046	0.014	8	82	198
2.0	0.945	0.059	0.017	1	51	108
3.0	0.945	0.059	0.017	0	27	56
4.0	0.945	0.059	0.017	0	8	29
5.0	0.945	0.059	0.017	0	10	21
6.0	0.945	0.059	0.017	0	7	11
7.0	0.945	0.059	0.017	0	1	4
8.0	0.945	0.059	0.017	0	0	4
9.0	0.630	0.370	0.358	1	2	3
Primary						
0.0	1.000	0.000	0.000	0	12	51
0.5	0.974	0.026	0.025	1	9	39
1.0	0.974	0.026	0.025	0	10	29
2.0	0.974	0.026	0.025	0	7	19
3.0	0.974	0.026	0.025	0	1	12
4.0	0.974	0.026	0.025	0	4	11
5.0	0.974	0.026	0.025	0	2	7
6.0	0.974	0.026	0.025	0	3	5
7.0	0.974	0.026	0.025	0	0	2
8.0	0.974	0.026	0.025	0	1	2
9.0	0.974	0.026	0.025	0	1	1

Whether this occurs for synthetic-patched CEAs cannot be determined by means of this study, because most of the synthetic-patched CEAs were performed more recently. The finding that 13 of the 20 ≥ 50% restenoses occurring after 5 years were located at or near the endarterectomy-produced common carotid step supports an earlier report.[22]

Although there were only 51 (0.4%) primarily closed CEAs in this study, they performed well, with no perioperative strokes and only one 50% or greater restenosis. Primary closure of arteriotomies limited to the bulb segment with a complete internal carotid endarterectomy end point is probably safe and advisable. On the other end of the spectrum, the 20 (1.5%) complex lesions reconstructed with saphenous vein interposition grafts also had acceptable outcomes, with no perioperative strokes or occlusions and one late restenosis. There is probably a place for interposition bypass grafting of complex or long, extensively diseased carotid arteries.

The CEAs were performed in a 15-year period, during which there was controversy about the effectiveness of CEA in stroke prevention, followed by confirmation of its value for both symptomatic and asymptomatic patients, and most recently, by the introduction of catheter-based angioplasty with or without stenting. Although new technology has and will supersede established vascular surgical techniques, it is imperative that when advising or offering patients new techniques, or when participating in prospective randomized trials evaluating them, physicians must be convinced that, based on current information, the new technology gives an acceptable outcome. The 2.1% 30-day stroke and mortality and the 0.4% major ipsilateral stroke and stroke-related death rates reported support the argument that standard CEA with highly frequent patch angioplasty reconstruction gives excellent results. Based on these results and the 1.2% ± 0.6% (95% CI) meta-analysis 30-day perioperative stroke rates for patched CEAs,[19] it is safe to project that any new technology, such as catheter-based balloon angioplasty with or without stenting, must have a 30-day stroke rate less than 2% and a stroke and mortality rate less than 3% to be considered a candidate for prospective evaluation of long-term restenosis and stroke outcomes.

CEA following a protocol of patch angioplasty reconstruction when the arteriotomy necessary to obtain a complete internal carotid endarterectomy end point extends beyond the bulb segment into the uniform diameter internal carotid gives excellent perioperative and long-term outcomes. Saphenous vein is superior to synthetic materials, particularly Dacron, for patch angioplasty reconstruction. Because of this, I currently use autologous greater saphenous vein when it is available, of adequate quality, and has a distended diameter greater than 3.5 mm. Dacron is an acceptable patch material when these vein criteria are not met.

REFERENCES

1. Sundt TM. Occlusive cerebrovascular disease. Philadelphia: Saunders; 1988. p. 197-8.
2. Imparato AM. The role of patch angioplasty after carotid endarterectomy. J Vasc Surg 1988;7:715-6.
3. Little JR, Bryerton BS, Furlan AJ. Saphenous vein patch grafts in carotid endarterectomy. J Neurosurg 1986;61:743-7.
4. Archie J. Prevention of early restenosis and thrombosis occlusion after carotid endarterectomy by saphenous vein patch angioplasty. Stroke 1986;17:901-5.
5. Hertzer NR, Beven EG, O'Hara PH. A prospective study of vein patch angioplasty during carotid endarterectomy. Ann Surg 1989;206:628-35.
6. Katz MM, Jones GT, Degenhardt J. The use of patch angioplasty to alter the incidence of carotid restenosis following thromboendarterectomy. J Cardiovasc Surg 1987;28:2-8.
7. Eikelboom BC, Ackerstaff RGA, Hoeneveld H, Ludwig JW, Teewwen C, Vermeulen FEE, et al. Benefits of carotid patching: a randomized study. J Vasc Surg 1988;7:240-7.
8. Lord RSA, Raj TB, Stary DL, Nash PA, Graham AR, Goh KH. Comparison of saphenous vein patch polytetrafluoroethylene patch and direct arteriotomy closure after carotid endarterectomy, Part 1: perioperative results. J Vasc Surg 1989;9:521-9.
9. Clagett GP, Patterson CB, Fisher DF Jr, Fry RE, Eidt JF, Humble TH, et al. Vein patch versus primary closure for carotid endarterectomy: a randomized prospective study in a selected group of patients. J Vasc Surg 1989;9:213-23.
10. Katz D, Snyder SO, Gandhi RH, Wheeler JR, Gregory RT, Gayle RG, et al. Long-term follow-up for recurrent stenosis: a prospective randomized study of expanded polytetrafluoroethylene patch angioplasty versus primary closure after carotid endarterectomy. J Vasc Surg 1994;19:198-205.
11. Vascular Research Group. Randomized controlled trial of patch angioplasty for carotid endarterectomy. Br J Surg 1993;80:1528-30.
12. AbuRahma AF, Khan JH, Robinson PA, Saiedy S, Sherl US, Boland JP, et al. Prospective randomized trial of carotid endarterectomy with primary closure and patch angioplasty with saphenous vein, jugular vein, and polytetrafluoroethylene: perioperative (30-day) results. J Vasc Surg 1996;24:998-1007.
13. Archie JP. Prospective randomized trials of carotid endarterectomy with primary closure and patch reconstruction: the problem is power. J Vasc Surg 1997;25:1118-9.
14. Archie JP. Patching with carotid endarterectomy: when to do it and what to use. Semin Vasc Surg 1998;11:24-9.
15. Archie JP. Patch graft closure following carotid endarterectomy. In Ernet CB, Stanley JC, editors. Current therapy in vascular surgery. 4th ed. In press, 1999.
16. Hertzer NR, O'Hara PH, Mascha EJ, Krajewski LP, Sullivan TM, Beren EG. Early outcome assessment for 2228 consecutive carotid endarterectomy procedures: The Cleveland Clinic experience from 1989 to 1995. J Vasc Surg 1997; 26:1-10.
17. Archie JP. Carotid endarterectomy outcome with vein or Dacron patch angioplasty and internal carotid shortening. J Vasc Surg 1999;29:654-64.
18. Archie JP. Carotid patching: what is the optimal patch material. In Goldstone J, editor. Perspectives in vascular surgery. Volume 10. New York: Thieme; 1999. p. 105-12.
19. Archie JP. Carotid endarterectomy outcomes. In Whittemore AD, editor. Advances in vascular surgery. Volume VII. St Louis: CV Mosby; 1999. p. 1-23.
20. Archie JP. Technique and clinical results of carotid stump back-pressure to determine selective shunting during carotid endarterectomy. J Vasc Surg 1991;13:319-27.
21. Archie JP. The outcome of external carotid endarterectomy during routine carotid endarterectomy. J Vasc Surg 1998;28:585-90.
22. Archie JP. The endarterectomy produced common carotid artery step: a harbinger of early emboli and late restenosis. J Vasc Surg 1996;23:932-9.
23. Archie JP, Green JJ. Saphenous vein rupture pressure rupture stress and carotid endarterectomy vein patch reconstruction. Surgery 1990;107:389-96.
24. Archie JP. Carotid endarterectomy saphenous vein patch rupture revisited: Selective utilization based on vein diameter. J Vasc Surg 1996;24:346-52.
25. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Eng J Med 1991;325:445-53.
26. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. N Engl J Med 1998;339:1415-25.
27. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 1995;1421-8.
28. Plestis KA, Kantis G, Haygood K, Earl N, Howell JF. Carotid endarterectomy with homologous vein patch angioplasty: a review of 1006 cases. J Vasc Surg 1996;24:109-19.
29. Schneider JR, Droste JS, Golan JF. Carotid endarterectomy in women versus men: patient characteristics and outcomes. J Vasc Surg 1997;25:890-8.

Submitted Sep 2, 1999; accepted Oct 25, 1999.